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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/210,031	12/11/1998	ATTILA T. LORINCZ	2629-4005US1	6182

7590

04/28/2003

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NEW YORK, NY 10154

EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/28/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/210,031

Applicant(s)

TANG ET AL.

Examiner

John S. Brusca

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 36-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 24 January 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/210031 is acceptable and a CPA has been established. An action on the CPA follows.
2. The amendment filed 25 June 2002 has been entered as noted in the Advisory Action mailed 11 July 2002.
3. The response originally filed 26 March 2003 and entered by the Office on 22 April 2003 is labeled "Preliminary Amendment" but does not contain an amendment to the specification.

### ***Drawings***

4. New corrected drawings are required in this application because of the deficiencies noted in the Form PTO-948 attached to the Office action mailed 13 March 2000. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Objections***

5. The objection to claims 36-54 in the Office action mailed 05 April 2002 is withdrawn in view of the amendment filed 25 June 2002.
6. Claim 56 is objected to because of the following informalities: In line 3, the claim recites "obtaining preserved a cell" and should be amended to recite "obtaining a preserved cell." Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

7. Claims 36-48, 51-54, 58, 59, and 61 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy et al. for reasons of record in the Office action mailed 05 April 2002.
8. Claims 49, 55-57, 60, and 68-74 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Weber in view of Harrison for reasons of record in the Office action mailed 05 April 2002.
9. Claims 62-66 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Wainwright for reasons of record in the Office action mailed 05 April 2002.
10. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 and further in view of Wainwright above, and further in view of Weber in view of Harrison for reasons of record in the Office action mailed 05 April 2002.
11. Applicant's arguments filed 26 March 2003 have been fully considered but they are not persuasive.

The declaration under 37 CFR 1.132 by Atilla T. Lorincz filed 26 March 2003 has been considered. The declaration employs an assay of nucleic acids by use of an antibody assay specific for RNA-DNA hybrids. The claimed subject matter is not limited to this assay and other forms of assay, such as direct hybridization of a labeled nucleic acid probe would be expected to work in the cited prior art media absent evidence to the contrary. It is further noted that the assay utilized in the declaration requires stability of RNA and antibodies for either the assay of RNA or

Art Unit: 1631

the assay of DNA since it is the RNA-DNA hybrid formed in each assay that is detected by antibodies specific for RNA-DNA hybrids. The claimed media and methods do not have the limitation of requiring utility for an antibody assay of RNA-DNA hybrids. The declaration performs assays after different periods of storage at room temperature, however it is noted that the claims are not limited to the length of time samples are stored in the media before assay.

A previous declaration under 37 CFR 1.132 by Atilla T. Lorincz filed 25 June 2002 appears to conflict with the declaration filed 26 March 2003 because the 25 June 2002 declaration shows in Tables 1 and 2 similar levels of detection of DNA at week 0 for all media tested and therefore suggest that the Dunphy media meet the limitations of the claimed invention. A significant signal was also obtained using Dunphy media at week 3. Tables 3 and 4 show reduced but still significant levels of detection at day 0 for RNA for the Dunphy media, with a greater reduction of signal at later times than seen in the DNA assay using Dunphy media.

The declaration states that EDTA does not improve nucleic acid stability, however the specification states on page 9 that chelating agents such as EDTA inhibit degradation of RNA and DNA. The motivation for addition of EDTA is that of Dunphy as discussed in the Office action mailed 23 October 2001, namely for a bacteriostatic effect.

### ***Double Patenting***

12. Claims 36-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-41, 46-55, 60-66, 71-75, and 80 of copending Application No. 09/598571 in view of Weber et al. (WO 94/02645, cited in the Form PTO 1449 received 07 June 1999) in view of Harrison for reasons of record in the Office action mailed 05 April 2002.

Art Unit: 1631

*Conclusion*

13. This is a CPA of applicant's earlier Application No. 09/210031. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

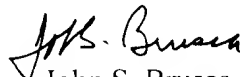
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Art Unit: 1631

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.



John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb  
April 28, 2003